510(k) SUMMARY

K131584

Date of Summary:	August 14, 2013
Product Name	IMDx Flu A/B and RSV for Abbott *m*2000
Sponsor	Intelligent Medical Devices, Inc. 19 Blackstone Street Cambridge, MA 02139
Correspondent	MDC Associates, LLC Fran White, Regulatory Consultant 180 Cabot Street Beverly, MA 01915

AUG 2 1 2013

Device Identification

Trade or Proprietary Name:	IMDx Flu A/B and RSV for Abbott *m*2000
Common or Usual Name:	Respiratory Virus Panel Nucleic Acid Assay System
Product Code:	OCC, OOI
Regulation Section:	21CFR866.3980
Device Class:	Class II
Panel:	Microbiology (83)

Intended Use

The IMDx Flu A/B and RSV for Abbott *m*2000 assay performed on the Abbott *m*2000 System is a qualitative *in vitro* diagnostic test designed for the detection of influenza A, influenza B, and RSV RNA directly from nasopharyngeal swabs from patients with signs and symptoms of respiratory infection. The assay detects RNA from influenza A, influenza B, and RSV (A and B) using real-time, reverse transcription polymerase chain reaction (rRT-PCR) and fluorogenic target specific hybridization for unique sequences in the viral target genomes. The IMDx Flu A/B and RSV for Abbott *m*2000 assay is intended for use as an aid in diagnosing influenza A and/or influenza B and/or RSV infection.

Negative results for influenza A, influenza B, or RSV do not preclude influenza virus or RSV infection and should not be used as the sole basis for diagnosis, treatment, or patient management decisions. Conversely, positive results do not rule-out bacterial infection or co-infection with other viruses. The agent(s) detected may not be the definite cause of disease. The use of additional laboratory testing and clinical presentation must be considered when diagnosing respiratory viral infection.

Performance characteristics for influenza A were established during the 2011-2012 and 2012-2013 influenza seasons when Influenza A/2009 H1N1 and Influenza A/H3 were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Device Description

The IMDx Flu A/B and RSV for Abbott *m*2000 assay uses nucleic acid extraction and purification technology, performed on the Abbott *m*2000*sp*, combined with rRT-PCR, performed with the Abbott *m*2000*rt*, to generate and detect amplified products from influenza A, influenza B, and RSV RNA that is isolated from clinical specimens.

The assay targets the influenza A matrix (M) gene, influenza B non-structural protein (NS1) gene, and RSV A and RSV B fusion (F) gene. The presence of a viral RNA target sequence is indicated by the fluorescent signal generated through the use of fluorescently labeled oligonucleotide probes on the Abbott *m*2000*rt* instrument. The probes do not generate a signal unless they are specifically bound to the amplified product. The amplification cycle at which fluorescent signal is detected by the Abbott *m*2000*rt* is inversely proportional to the viral RNA target concentration present in the original sample.

An RNA bacteriophage species unrelated to influenza A, influenza B, or RSV is introduced into each specimen during sample preparation to serve as a process control. The process control bacteriophage is lysed simultaneously with influenza A, influenza B and RSV A and RSV B in the sample, and amplified in the same reaction as the viral RNA targets using rRT-PCR. The process control serves to demonstrate that the entire assay process has proceeded correctly for each sample.

Substantial Equivalency

The IMDx Flu A/B and RSV for Abbott *m*2000 assay is substantially equivalent to the Verigene® Respiratory Virus Plus Nucleic Acid Test on the Verigene® System (RV+) (K103209). The tables below compare the characteristics of the IMDx Flu A/B and RSV for Abbott m2000 Assay (New Device) and the Nanosphere Verigene Assay (Predicate Device).

Similarity to Predicate Device

Characteristic	**IMDx Flu A/B and RSV for Abbott *m*2000**	**Verigene® Respiratory Virus Plus Nucleic Acid Test on the Verigene® System (RV+)**
510(k)	K131584	K103209
Regulation	866.3980	866.3980
Product Code	OCC, OOI	OCC; NSU
Device Class	Class II	Class II
Intended use	The IMDx Flu A/B and RSV for Abbott *m*2000 assay performed on the Abbott *m*2000 System is a qualitative *in vitro* diagnostic test designed for the detection of influenza A, influenza B, and RSV RNA directly from nasopharyngeal swabs from patients with signs and symptoms of respiratory infection. The assay detects RNA from influenza A, influenza B, and RSV (A and B) using real-time, reverse transcription polymerase chain reaction (rRT-PCR) and fluorogenic target specific hybridization for unique sequences in the viral target genomes. The IMDx Flu A/B and RSV for Abbott *m*2000 assay is intended for use as an aid in diagnosing influenza A and/or influenza B and/or RSV infection.	The Verigene® Respiratory Virus Plus Nucleic Acid Test (RV+) on the Verigene® System is a qualitative nucleic acid multiplex test intended to simultaneously detect and identify multiple respiratory virus nucleic acids in nasopharyngeal (NP) swab specimens from individuals with signs and symptoms of respiratory tract infection. The following virus types and subtypes are identified using the RV+: influenza A, influenza A subtype H1, influenza A subtype H3, 2009 H1N1, influenza B, Respiratory Syncytial Virus (RSV) subtype A, and RSV subtype B. The test is not intended to detect influenza C virus. Detecting and identifying specific viral nucleic acids from individuals exhibiting signs and symptoms of respiratory infection aids in the diagnosis of respiratory viral

Characteristic	IMDx Flu A/B and RSV for Abbott *m*2000	Verigene® Respiratory Virus Plus Nucleic Acid Test on the Verigene® System (RV+)
	Negative results for influenza A, influenza B, or RSV do not preclude influenza virus or RSV infection and should not be used as the sole basis for diagnosis, treatment, or patient management decisions. Conversely, positive results do not rule-out bacterial infection or co-infection with other viruses. The agent(s) detected may not be the definite cause of disease. The use of additional laboratory testing and clinical presentation must be considered when diagnosing respiratory viral infection. Performance characteristics for influenza A were established during the 2011-2012 and 2012-2013 influenza seasons when influenza A/2009 H1N1 and influenza A/H3 were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary. If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.	infection, if used in conjunction with other clinical and laboratory findings. Negative results for influenza A, influenza B, or RSV do not preclude influenza virus or RSV infection and should not be used as the sole basis for diagnosis, treatment, or patient management decisions. Conversely, positive results do not rule-out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. The use of additional laboratory testing and clinical presentation must be considered in order to obtain the final diagnosis of respiratory viral infection. Performance characteristics for influenza A Virus were established when influenza A/H3, A/H1, and 2009 H1N1 were the predominant influenza A viruses circulating. These characteristics may vary when other influenza A viruses are emerging. If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions used specifically for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.
Sample type	Nasopharyngeal swabs	Nasopharyngeal swabs
Sample Preparation	Automated extraction of nucleic acids	Automated extraction of nucleic acids
Test Principle	Real-time, reverse transcription polymerase chain reaction (rRT-PCR) DNA amplification	Real-time, reverse transcription polymerase chain reaction (RT-PCR) DNA amplification
Targets Detected	influenza A influenza B RSV A/B	influenza A influenza B RSV A RSV B
Controls	Positive Control Negative Control Process Control	Positive Control Negative Control Inhibition Control Internal Control
Instrumentation	Abbott® *m*2000™ System (K092705)	Verigene ®System (K070804)

Differences from Predicate Device

Characteristic	IMDx Flu A/B and RSV for Abbott *m*2000	Verigene® Respiratory Virus Plus Nucleic Acid Test on the Verigene® System (RV+)
Throughput	Batch	Single use cassette
Viral Sub-Typing	No	Yes

These differences do not affect substantial equivalency of the IMDx Flu A/B and RSV for Abbott *m*2000 and Verigene® Respiratory Virus Plus Nucleic Acid Test. Both assays detect influenza A, influenza B and RSV viral nucleic acids from nasopharyngeal swabs and the assays have comparable intended uses. The differences noted above do not change the intended use and do not raise different questions of safety and effectiveness.

Performance Characteristics

Clinical Agreement

The performance of the IMDx Flu A/B and RSV for Abbott *m*2000 assay was assessed compared to viral culture followed by direct fluorescent antibody (DFA) detection during the course of two (2) influenza seasons (2011-2012 and 2012-2013). For the 2011-2012 season (collected February–April 2012), four (4) geographically diverse test sites within the United States prospectively collected influenza A/B and RSV samples. Samples enrolled for this study were nasopharyngeal swabs collected for routine influenza testing. A total of four hundred and ninety seven (497) specimens were included in the final data set and analyzed for product performance.

For the 2012-2013 season (collected March–April 2013), three (3) geographically diverse test sites within the United States prospectively collected influenza A/B and RSV samples. Samples enrolled for this study were nasopharyngeal swabs collected for routine influenza testing. A total of four hundred and thirty-five (435) specimens were included in the final data set and analyzed for product performance.

Patient Population

Age and Gender Distribution				
Age	Female		Male	
	2011-2012	2012-2013	2011-2012	2012-2013
≤5 years	84 (30.1%)	71 (31.8%)	76 (34.7%)	101 (47.6%)
6 – 21 years	38 (13.6%)	29 (13.0%)	45 (20.5%)	28 (13.2%)
22 – 59 years	96 (34.4%)	76 (34.1%)	63 (28.9%)	44 (20.7%)
≥ 60 years	61 (21.9%)	47 (21.1%)	34 (15.5%)	39 (18.4%)
Season Totals	279	223	218	212
Overall Totals	502		430	

Between the two influenza seasons, a total of 932 NPS samples were tested and analyzed for performance. Results are shown below. Discordant samples were tested using the Nanosphere Verigene® Respiratory Virus Plus Nucleic Acid Test (RV+) on the Verigene® System and subsequent results are documented in the footnote.

Influenza A Clinical Agreement Summary

All Sites Influenza A		Viral Culture				
		Positive	Negative	Total		
IMDx Flu A/B and RSV for Abbott *m*2000 Assay	Positive	164	33[1]	197	Sensitivity	97.6% (94% - 99%) 95% CI
	Negative	4[2]	731	735	Specificity	95.7% (94% - 97%) 95%CI
	Total	168	764	932		

[1]25/33 samples were confirmed as influenza A Positive using an FDA cleared molecular assay.
[2]4/4samples were confirmed as influenza A Negatives using an FDA cleared nucleic acid test.

Influenza B Clinical Agreement Summary

All Sites Influenza B		Viral Culture				
		Positive	Negative	Total		
IMDx Flu A/B and RSV for Abbott *m*2000 Assay	Positive	67	24[3]	91	Sensitivity	97.1% (90% - 99%) 95% CI
	Negative	2	839	841	Specificity	97.2% (96% - 98%) 95%CI
	Total	69	863	932		

[3]20/24 samples were confirmed as influenza B Positive using an FDA cleared molecular assay.

RSV Clinical Agreement Summary

All Sites RSV		Viral Culture				
		Positive	Negative	Total		
IMDx Flu A/B and RSV for Abbott *m*2000 Assay	Positive	104	58[4]	162	Sensitivity	97.2% (92% - 99%) 95% CI
	Negative	3[5]	767	770	Specificity	93.0% (91% - 95%) 95%CI
	Total	69	825	932		

[4]39/58 samples were confirmed as RSV Positive using an FDA cleared molecular assay.
[5]1/3 samples were confirmed as RSV Positive using an FDA cleared molecular assay.

Analytical Performance

Reproducibility

A sixteen-member panel was used for the reproducibility study. The panel was made with 2 influenza A strains (one H1N1 and one H3N2), one influenza B strain, one RSV-A strain and one RSV-B strain. Each strain was spiked in M4RT viral transport medium at three different approximate target levels: Moderate Positive (~2-3X LoD), Low Positive (1X LoD) and High Negative (0.2 - 0.8X LoD). Panel members were formulated with only one target present (influenza A, influenza B, RSV-A, RSV-B). A negative sample (transport medium only) was also included.

Each panel member was tested in replicates of three, twice a day for five days, for a total of 10 experiment runs. Testing was conducted at three sites. At each site, the runs were performed by two operators, with each operator performing one run each day.

To conduct the site-to-site reproducibility study, panel members (moderate positive, low positive, high negative, and negative) for each virus were randomized and sample identities were blinded to the user. Each panel member was tested in replicates of three, twice a day for five days, for a total of 10 runs. Testing was conducted at three sites. At each site, the runs were performed by two operators, with each operator performing one run each day. The entire study was conducted using the same instrument system (Abbott *m*2000*sp* and *m*2000*rt*) at each site, and one reagent lot of

the IMDx Flu A/B and RSV for Abbott *m*2000 kits. The aggregate percent CV values across all sites were ≤ 3.7% for all targets, and for all concentrations tested.

		Site 1		Site 2		Site 3		All 3 Sites	
Specific Panel Member	Level	% Agreement (Agreement with expected result)	Avg. CN (%CV)	% Agreement (Agreement with expected result)	Avg. CN (%CV)	% Agreement (Agreement with expected result)	Avg. CN (%CV)	% Agreement (95% CI)	Avg. CN (%CV)
influenza A (H1N1)	Moderate Positive	100.00 (30/30)	33.52 (2.46)	100.00 (30/30)	34.28 (2.17)	93.33 (28/30)	33.76 (2.58)	97.78 (94.73 – 100.00)	33.85 (2.28)
	Low Positive	100.00 (30/30)	34.95 (1.67)	100.00 (30/30)	35.83 (2.41)	96.67 (29/30)	35.16 (3.21)	97.78 (94.73 – 100.00)	35.31 (2.35)
	High Negative	36.67 (11/30)	36.92 (4.67)	33.33 (10/30)	37.88 (1.99)	33.33 (10/30)	37.43 (3.31)	34.44 (24.63 – 44.26)	37.38 (3.04)
Influenza A (H3N2)	Moderate Positive	100.00 (30/30)	33.26 (1.77)	100.00 (30/30)	33.65 (1.37)	100.00 (30/30)	33.31 (1.59)	100.00 (100.00 – 100.00)	33.41 (1.53)
	Low Positive	100.00 (30/30)	34.61 (1.29)	100.00 (30/30)	34.85 (1.22)	100.00 (30/30)	35.04 (1.96)	100.00 (100.00 – 100.00)	34.83 (1.50)
	High Negative	6.67 (2/30)	36.53 (1.41)	16.67 (5/30)	37.31 (1.81)	20.00 (6/30)	37.28 (1.88)	14.44 (7.18 – 21.71)	37.04 (1.72)
Influenza B	Moderate Positive	100.00 (30/30)	32.25 (1.37)	96.67 (29/30)	32.18 (1.33)	100.00 (30/30)	32.22 (0.79)	98.89 (96.72 – 100.00)	32.22 (1.13)
	Low Positive	96.67 (29/30)	33.91 (0.81)	96.67 (29/30)	33.89 (1.21)	73.33 (22/30)	33.89 (1.00)	88.89 (82.40 – 95.38)	33.90 (1.01)
	High Negative	30.00 (9/30)	34.53 (1.07)	36.67 (11/30)	34.74 (0.90)	53.33 (16/30)	34.50 (1.07)	40.00 (29.88 – 50.12)	34.53 (0.93)
RSV-A	Moderate Positive	100.00 (30/30)	32.62 (3.52)	100.00 (30/30)	32.10 (4.82)	93.33 (28/30)	32.47 (2.60)	97.78 (94.73 – 100.00)	32.39 (3.64)
	Low Positive	96.67 (29/30)	33.63 (2.15)	96.67 (29/30)	33.57 (2.47)	100.00 (30/30)	33.15 (3.21)	97.78 (94.73 – 100.00)	33.45 (2.52)
	High Negative	6.67 (2/30)	34.93 (2.80)	6.67 (2/30)	35.03 (1.90)	23.33 (7/30)	34.50 (3.07)	12.22 (5.46 – 18.99)	34.82 (2.48)
RSV-B	Moderate Positive	96.67 (29/30)	32.68 (1.90)	100.00 (30/30)	32.39 (2.14)	90.00 (27/30)	31.78 (2.54)	95.56 (91.30 – 99.81)	32.29 (2.18)
	Low Positive	86.67 (26/30)	35.20 (1.91)	86.67 (26/30)	35.21 (1.50)	70.00 (21/30)	34.63 (2.14)	81.11 (73.02 – 89.20)	35.02 (1.83)
	High Negative	70.00 (21/30)	36.78 (0.95)	86.67 (26/30)	36.55 (1.20)	80.00 (24/30)	36.06 (1.76)	78.89 (70.46 – 87.32)	36.23 (0.83)
Negative	Negative	100.00 (30/30)	-1.00 (0.00)	100.00 (30/30)	-1.00 (0.00)	100.00 (30/30)	-1.00 (0.00)	100.00 (100.00 – 100.00)	-1.00 (0.00)

Analytical Sensitivity (Limit of Detection)

The Analytical Sensitivity, or Limit of Detection (LoD), is defined as the concentration at which ≥ 95% of all replicates tested positive. The LoD for the IMDx Flu A/B and RSV for Abbott *m*2000 assay was determined using two strains of influenza A, two strains of influenza B, one strain of RSV-A, and one strain of RSV-B. Volumes of each dilution tested were in accordance with sample processing instructions provided in this package insert, and are representative of the amount of material collected by swab sampling methods. The results are summarized in the table below.

Strain	LoD
Influenza A/Swine/NY/02/09 (H1N1)	3.9×10^{0} $TCID_{50}$/mL
Influenza A/Brisbane/10/07 (H3N2)	1.51×10^{1} $TCID_{50}$/mL
Influenza B/Florida/04/2006	2.82×10^{-2} $TCID_{50}$/mL
RSV A (RSVA Type A)	4.17×10^{0} $TCID_{50}$/mL
RSV B CH93-(18)-18	1.65×10^{0} $TCID_{50}$/mL

Analytical Reactivity

A panel of 55 strains (31 influenza A, 15 influenza B, and 9 RSV) was tested for their ability to be detected by the IMDx Flu A/B and RSV for Abbott *m*2000 assay. Each strain was diluted in viral transport media and tested in triplicate. All strains tested were positive for their representative assay targets.

Strain	Concentration Tested
A/California/7/2009 (H1N1)	1.07×10^{2} $CEID_{50}$/mL
A/New Caledonia/20/99 (H1N1)	2.62×10^{1} $TCID_{50}$/mL
A/Solomon Islands/3/2006 (H1N1)	6.19×10^{0} $TCID^{50}$/mL
A/PR/8/34 (H1N1)	1.56×10^{0} $TCID_{50}$/mL
A/WS/33 (H1N1)	$4.88x\ 10^{-1}$ $CEID_{50}$/mL
A/Brisbane/59/07 (H1N1)	2.49×10^{1} $TCID_{50}$/mL
A/Swine/Canada/6294/09 (H1N1)	6.57×10^{0} $TCID_{50}$/mL
A/NJ/8/76 (H1N1)	5.91×10^{0} $TCID_{50}$/mL
A/NWS/33 (H1N1)	4.05×10^{0} $CEID_{50}$/mL
A/FM/1/47 (H1N1)	1.20×10^{1} $CEID_{50}$/mL
A/Mal/302/54 (H1N1)	1.86×10^{0} $CEID_{50}$/mL
A/Denver/1/57 (H1N1)	7.48×10^{1} $CEID_{50}$/mL
A/Virginia/ATCC2/2009 (H1N1)	5.91×10^{0} $CEID_{50}$/mL
A/Wisconsin/67/05 (H3N2)	4.85×10^{1} $TCID_{50}$/mL
A/MRC2 (H3N2)	1.56×10^{2} $CEID_{50}$/mL
A/Aichi/2/26 (H3N2)	2.85×10^{2} $CEID_{50}$/mL
A/Victoria/3/75 (H3N2)	8.87×10^{0} $CEID_{50}$/mL
A/Port Chalmers/1/73 (H3N2)	3.64×10^{2} $TCID_{50}$/mL
A/Perth/16/09 (H3N2)	3.79×10^{0} $TCID_{50}$/mL
A/Hong Kong/8/68 (H3N2)	5.10×10^{0} $TCID_{50}$/mL
A/Rhode Island/01/2010 (H3N2)	1.50×10^{3} $TCID_{50}$/mL
A/New York/55/2004 (H3N2)	2.58×10^{2} $TCID_{50}$/mL
A/Uruguay/716/2007 (H3N2)	9.79×10^{2} $TCID_{50}$/mL
A/Florida/2/2006 (H3N2)	2.28×10^{2} $TCID_{50}$/mL
A/Victoria/361/2011 (H3N2)	3.84×10^{2} $CEID_{50}$/mL
A/Indiana/10/2011 (H3N2v)	4.61×10^{2} $TCID_{50}$/mL
A/Texas/71/2007 (H3N2v)	1.56×10^{0} $TCID_{50}$/mL
A/Indiana/08/2011 (H3N2v)	2.60×10^{0} $TCID_{50}$/mL
B/Mass/3/66	1.78×10^{1} $CEID_{50}$/mL
B/Allen/45	1.00×10^{4} $CEID_{50}$/mL
B/Lee/40	1.00×10^{4} $CEID_{50}$/mL
B/Maryland/1/59	1.00×10^{3} $CEID_{50}$/mL
B/Florida/07/04	1.82×10^{1} $TCID_{50}$/mL
B/Florida/02/2006	3.43×10^{0} $TCID_{50}$/mL
B/Hong Kong/5/72	1.19×10^{1} $CEID_{50}$/mL
B/RUSSIA/69	9.99×10^{0} $CEID_{50}$/mL
B/TAIWAN/2/62 (93-02)	1.00×10^{3} $CEID_{50}$/mL
B/GL/1739/54	1.00×10^{6} $CEID_{50}$/mL
B/Brisbane/60/08	2.01×10^{-1} $TCID_{50}$/mL
B/Wisconsin/01/2010	3.20×10^{0} $CEID_{50}$/mL
B/Santiago/4360/2007	1.61×10^{0} $CEID_{50}$/mL
B/Texas/39/2006	5.91×10^{1} $CEID_{50}$/mL
B/Ohio/01/2005	1.19×10^{2} $CEID_{50}$/mL
RSV/A2	7.42×10^{0} $TCID_{50}$/mL
RSVA/Long	7.08×10^{3} $TCID_{50}$/mL
RSVA 1998/12-21	2.10×10^{1} $TCID_{50}$/mL
RSVA 1998/3-2	6.97×10^{-1} $TCID_{50}$/mL
RSVA 2001/2-20	4.09×10^{0} $TCID_{50}$/mL
RSVA 2001/3-12	9.97×10^{0} $TCID_{50}$/mL
RSVB/9320	8.39×10^{0} $TCID_{50}$/mL
RSVB/WV/14617/85	1.79×10^{0} $TCID_{50}$/mL
RSVB/WASH/18537/62	1.97×10^{0} $TCID_{50}$/mL

Strain	Concentration Tested
A/duck/Pennsylvania/10218/84 (H5N2)*	23 pg/µL
A/HongKong/33982/2009 (H9N2)*	57 pg/µL

*Denotes testing on purified genomic RNA

Analytical Specificity: Cross Reactivity

A panel of 36 organisms from respiratory pathogens or human microbiota, and purified human DNA were tested at approximately $1x10^6$ CFU/mL for bacteria, $1x10^5$ $TCID_{50}$/mL for viruses, and $1.0x10^4$ copies/mL for human DNA using the IMDx Flu A/B and RSV for Abbott *m*2000 assay. No cross reactivity was observed for the IMDx Flu A/B and RSV for Abbott *m*2000 assay.

Microbial Interference

The same panel of 36 organisms from respiratory pathogens or human microbiota, and purified human DNA at concentrations of approximately $1x10^6$ CFU/mL for bacteria, $1x10^5$ $TCID_{50}$/mL for viruses, and $1.0x10^4$ copies/mL for human DNA were added to sample tubes containing one of six target organisms; two influenza A, two influenza B and two RSV strains in viral transport medium. The two influenza A strains used for this study were influenza A/Swine/NY/02/2009 (H1N1) and influenza A/Brisbane/10/2007 (H3N2). The two influenza B strains used for this study were influenza B/Florida/04/2006 (VI/87) and influenza B/Malaysia/2506/2004 (YA/88). The two RSV strains used for this study were RSV A Type A and RSV B CH93-18(18). Assay analytes were present in the samples at concentrations corresponding to 2-3X LoD. Each of the six strains was tested against the 36 member panel in triplicate using the IMDx Flu A/B and RSV for Abbott *m*2000 assay. No evidence of interference was observed.

Organism
Adenovirus type 1
Adenovirus type 7A
Bordetella pertussis
Candida albicans
Coronavirus
Corynebacterium ulcerans
Coxsackievirus
Cytomegalovirus (CMV)
Epstein-Barr Virus (EBV)
Escherichia coli
Haemophilus influenza
Human Herpes Virus 6 (HHV6), Z29 strain
Human Herpes Virus 7 (HHV7), SB Strain
Human genomic DNA*
Klebsiella pneumoniae
Lactobacillus acidophilus Z048
Legionella pneumoniae
Moraxella catarrhalis
Mycoplasma hominis
Mycoplasma pneumoniae
Neisseria meningitidis
Neisseria gonorrhoeae
Parainfluenza virus 1
Parainfluenza virus 2
Parainfluenza virus 3

Organism
Pseudomonas aeruginosa
Staphylococcus aureus MRSA
Staphylococcus aureus MSSA
Staphylococcus epidermidis MRSE
Streptococcus pneumoniae
Streptococcus salivarius
Measles Virus
Mumps
Metapneumovirus 3 type B1
Metapneumovirus 9 type A1
Rhinovirus
Influenza A/Swine/NY/02/09**
Influenza A/Brisbane/10/07**
Influenza B/Florida/04/06**
Influenza B/Malaysia/2506/04**
RSVA Type A strain**
RSVB CH93-18(18)**

*Human Genomic DNA ≥ 1.0 x10^4 copies/mL

** Tested in competitive interference study.

Competitive Interference

A competitive interference, or co-infection, study was performed to test whether a high titer of one virus would interfere with the detection of a second target virus that was present at low titer. High titered samples were formulated at concentrations of 2 x 10^4 $TCID_{50}$/mL, and low titered targets were formulated at a concentration of approximately 2-3X LoD for that strain. One strain each of influenza A, influenza B, and RSV was used in this study. Each virus type was tested at low titers in conjunction with a high titer of each of the other two virus types, and samples were tested in triplicate. There was no observed interference with co-infection samples from the competitive interference study; high concentration targets did not interfere with the detection of a second target that was near LoD.

Potentially Interfering Substances

The susceptibility of the IMDx Flu A/B and RSV for Abbott *m*2000 assay to interference by elevated levels of endogenous substances or exogenous preparations was evaluated. Six viral strains were evaluated: two influenza A strains: A/Swine NY/02/09 (H1N1) and A/Brisbane/10/07 (H3N2); two influenza B strains: B/Florida/04/07 and B/Malaysia/2506/04; two RSV strains: RSV-A and RSV-B CH93-(18)-18. These test organisms were diluted to a concentration of 2-3X LoD using M4RT viral transport medium. The test panel consisted of substances that may be found in nasopharyngeal swab specimens (listed in the Table below). Testing was conducted using one lot of IMDx Flu A/B and RSV for Abbott *m*2000 amplification reagents. Substances were diluted in viral transport media to concentrations that would either replicate or exceed the highest concentration expected to be found in a clinical sample. Each of the 6 viral strains was tested in triplicate in the presence of each substance. No interference in the performance of the IMDx Flu A/B and RSV for Abbott *m*2000 assay was observed.

Substance	Active Ingredients and Potential Interferents in Substance
Nasal Sprays	Oxymetazoline
	Phenylephrine
	Sodium chloride (with preservatives)
Nasal Gel	Galphimia glauca Luffa opperculata Sulfur
Nasal corticosteroids	Dexamethasone

Substance	Active Ingredients and Potential Interferents in Substance
	Fluticasone
	Mometasone furoate
	Budesonide
	Flunisolide
	Triamcinolone acetonide
	Beclomethasone
NSAIDs	Aspirin
	Ibuprofen
	Naproxen
Acetaminophen	Acetaminophen
Relenza®	Zanamivir
Antibacterial, systemic	Tobramycin
Benzocaine	Benzocaine
Antibiotic nasal ointment	Mupirocin
Allergy medicine	Histamine hydrochloricum
Mucus (bovine)	Mucin protein, type I-S
Blood (Human)	Whole Blood with EDTA

In addition to the substances listed above, the FluMist® influenza vaccine was tested for its ability to interfere with the IMDx Flu A/B and RSV for Abbott *m*2000 assay. FluMist contains live attenuated reassortants of each of the three strains: Influenza A/California/07/2009 (H1N1), Influenza A/Perth/16/2009 (H3N2), and Influenza B/Brisbane/60/2008 and is administered intranasally. Initial testing of FluMist® influenza vaccine at a concentration of $10^{6.5}$ to $10^{7.5}$ units gave detected signals for influenza A, and influenza B, but the influenza A and B CN values were higher than expected, indicating that the assay detected the viruses present in the vaccine. When the vaccine was diluted to 1 x 10^{-8} and then tested using the IMDx Flu A/B and RSV for Abbott *m*2000 assay, influenza A and B were not detected. When the diluted vaccine was used for interference studies, no interference was observed; all test strains of influenza A, influenza B, and RSV were detected as expected.

Conclusion

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

INTELLIGENT MEDICAL DEVICES, INC.
C/O FRAN WHITE, MDC Associates, LLC.
180 CABOT STREET
BEVERLY MA 01915

August 21, 2013

Re: K131584
Trade/Device Name: IMDx Flu A/B and RSV for Abbott *m*2000
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory viral panel multiplex nucleic acid assay
Regulatory Class: II
Product Code: OCC, OOI
Dated: May 29, 2013
Received: May 31, 2013

Dear Ms. White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sally A. Hojvat -S

Sally Hojvat, M.Sc., Ph.D.
Director, Division of Microbiology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k131584

Device Name: IMDx Flu A/B and RSV for Abbott *m*2000

Indications for Use:

The IMDx Flu A/B and RSV for Abbott *m*2000 assay performed on the Abbott *m*2000 System is a qualitative *in vitro* diagnostic test designed for the detection of influenza A, influenza B, and RSV RNA directly from nasopharyngeal swabs from patients with signs and symptoms of respiratory infection. The assay detects RNA from influenza A, influenza B, and RSV (A and B) using real-time, reverse transcription polymerase chain reaction (rRT-PCR) and fluorogenic target specific hybridization for unique sequences in the viral target genomes. The IMDx Flu A/B and RSV for Abbott *m*2000 assay is intended for use as an aid in diagnosing influenza A and/or influenza B and/or RSV infection.

Negative results for influenza A, influenza B, or RSV do not preclude influenza virus or RSV infection and should not be used as the sole basis for diagnosis, treatment, or patient management decisions. Conversely, positive results do not rule-out bacterial infection or co-infection with other viruses. The agent(s) detected may not be the definite cause of disease. The use of additional laboratory testing and clinical presentation must be considered when diagnosing respiratory viral infection.

Performance characteristics for influenza A were established during the 2011-2012 and 2012-2013 influenza seasons when Influenza A/2009 H1N1 and Influenza A/H3 were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostic Devices and Radiological Health (OIR)

Tamara V. Feldblyum -S
2013.08.15 15:53:36 -04'00'